Proposed Decision Memo for Smoking & Tobacco Use Cessation Counseling (CAG-00241N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that smoking and tobacco use cessation counseling, based on the current U.S. Public Health Service (PHS) Guideline, is reasonable and necessary for a patient with a disease or an adverse health effect that has been found by the U.S. Surgeon General to be linked to tobacco use, or who is taking a therapeutic agent whose metabolism or dosing is affected by tobacco use as based on FDA-approved information. The counseling may only be provided by individuals trained in tobacco use cessation counseling.

Minimal counseling is already covered at each evaluation and management (E&M) visit. Beyond that, Medicare proposes to cover 2 cessation attempts per year. Each attempt may include a maximum of four intermediate or intensive sessions, with the total annual benefit covering up to 8 sessions in a 12 month period. The practitioner and patient have flexibility to choose between intermediate or intensive cessation strategies for each attempt.

CMS requests public comments on this proposed decision memorandum pursuant to Section 731 of the Medicare Modernization Act. After considering the public comments, we will issue a final decision memorandum.

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Proposed Decision Memo

To: Administrative File: CAG 00241N
Smoking and Tobacco Use Cessation Counseling

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Subject: Proposed Coverage Decision Memorandum for Smoking and Tobacco use Cessation Counseling

Date: December 23, 2004

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

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Minimal counseling is already covered at each evaluation and management (E&M) visit. Beyond that, Medicare proposes to cover 2 cessation attempts per year. Each attempt may include a maximum of four intermediate or intensive sessions, with the total annual benefit covering up to 8 sessions in a 12 month period. The practitioner and patient have flexibility to choose between intermediate or intensive cessation strategies for each attempt.

CMS requests public comments on this proposed decision memorandum pursuant to Section 731 of the Medicare Modernization Act. After considering the public comments, we will issue a final decision memorandum.

II.Background

Tobacco continues to be the leading cause of preventable death in the United States. In 1964, the Surgeon General of the U.S. Public Health Service issued the report of his Advisory Committee on Smoking and Health, officially recognizing that cigarette smoking is a cause of cancer and other serious diseases. Though smoking rates have significantly declined, 9.3 percent (95% CI = ± 0.8) of the population age 65 and older smokes cigarettes.[1] Approximately 440,000 people die annually from smoking related disease, with 68% (300,000) age 65 or older.[2] Many more people of all ages suffer from serious illness caused from smoking, leading to disability and decreased quality of life.[3] Reduction in smoking prevalence is a national objective in Healthy People 2010 (U.S. Department of Health and Human Services [USDHHS] 2000).

Smoking is associated with a variety of adverse health effects. The 2004 Surgeon General's report on the health consequences of smoking expanded the list of diseases causally linked to smoking.[4] Smoking causes heart disease, stroke, multiple cancers, respiratory diseases, gastrointestinal disease, cataracts and osteoporosis (in postmenopausal women).[4] Smoking can cause clinically significant tobacco-drug interactions. In the elderly and disabled Medicare populations, smokers report worse physical and mental functional status than people who never smoked.[5] Smoking affects the function of the immune system and is also associated with higher levels of chronic inflammation.[4] On average, nonsmokers survived 1.6 – 3.9 years longer than those who have ever smoked.[6] Using smokeless tobacco is not a good substitute for smoking, as it is known to similarly cause cancer.[7]

The direct costs of cigarette smoking to the health care system are substantial. In 1993, smoking cost the Medicare program about $14.2 billion, or approximately 10 percent of Medicare's total budget.[8] In the general population, direct medical costs for the detection, treatment and rehabilitation of persons with smoking attributable clinical diseases constitute 6 to 8 percent of the total annual expenditures for health care, with an upper limit suggested as high as 14 percent.[4]

Abstinence from tobacco improves health. In 1990, Surgeon General Antonia C. Novello issued The *Health Benefits of Smoking Cessation*, a comprehensive and rigorous review of the evidence that concluded: "…the benefits of cessation extend to quitting at older ages."[9] Smoking cessation in older adults leads to significant risk reduction and other health benefits, even in those who have smoked for years.[4,9,10,11] These benefits include:

- Prevention or reduction in the risk of cardiovascular disease, with a decline in risk of death within the first year after quitting.[10,12,13,14]
- Prevention or reduction in the risk of respiratory diseases.[15]
- Prevention or reduction in the risk of many cancers.[4,16]
- Extending life and increasing a level of independent functioning that is less restricted or impaired.[17,18]

Tobacco abstinence can be accomplished. About 10% of elderly smokers quit each year, with only a one percent relapse rate.[19] A report by the CDC (2002) estimated that about 57% of smokers age 65 and over report a desire to quit.[20] Smoking cessation assistance options have expanded over time. Current options include self-help literature, quit-smoking classes and support groups, individual or group counseling, and pharmacotherapies. Pharmacotherapies include over the counter medications such as nicotine replacement therapy in the form of gum or patches and prescription medications including nicotine replacement via nasal spray and inhaler, and bupropion.

In June, 2004, the Partnership for Prevention requested a national coverage decision for tobacco cessation counseling as recommended in the U.S. Department of Health and Human Services, Public Health Service (PHS) 2000 *Clinical Practice Guideline. Treating Tobacco Use and Dependence* (PHS 2000 Guideline).

III. History of Medicare Coverage

The Centers for Medicare & Medicaid Services (CMS) has not previously issued a National Coverage Determination for smoking cessation counseling. Local Medicare contractors currently have discretion to cover these services when they determine them to be medically necessary for the individual patient. The benefit categories for smoking cessation counseling are the following, as defined in the Social Security Act:

Section 1861(s)(1)	Physicians services.
Section 1861(s)(2)(A)	Service furnished as an incident to a physician's professional service.
Section 1861(s)(2)(B)	Outpatient hospital services.
Section 1861(s)(2)(E)	Rural health clinic services and federally qualified health center services.
Section 1861(s)(2)(K)	Services which would be physicians' services if furnished by a physician and which are performed by a physician assistant (subsection (i)), nurse practitioner or clinical nurse specialist (subsection (ii)).
Section 1861(s)(2)(M)	Qualified psychologist services.
Section 1861(s)(2)(N)	Clinical social worker services.

Self-administerable pharmacotherapy for the purpose of tobacco use cessation is not a currently a covered benefit. The Medicare Modernization Act (MMA) of 2003 does authorize a drug benefit relating to certain smoking cessation agents beginning in January of 2006.

IV. Timeline of Recent Activities

On June 23, 2004, CMS accepted a request from the President of Partnership for Prevention to expand coverage for tobacco cessation counseling. Their letter requested that CMS cover tobacco cessation counseling for Medicare beneficiaries with smoking related disease or symptoms of smoking related disease as detailed in the U.S. Department of Health and Human Services, Public Health Service (PHS) 2000 *Clinical Practice Guideline, Treating Tobacco Use and Dependence*.

June 23, 2004	Formal request accepted and review initiated.
June 23, 2004	Request letter posted on Coverage website. Public comment period for 30 days begins.
August 11, 2004	Comments from the 30 day public comment period posted on Coverage web site.

V. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical questions relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits. The three stages of assessment are detailed in Appendix A.

The methodological principles presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

VI. Evidence

A. Introduction

Smoking cessation (abstinence) information is a substitute endpoint (surrogate) for the important clinical issue of improved health outcomes. The effectiveness of tobacco use counseling can be judged based on the ability to bring about abstinence, as abstinence has been shown to improve health outcomes. Abstinence is the chief outcome measure in many studies of the effectiveness of cessation counseling. While permanent abstinence after quitting is the most desirable outcome, tobacco abuse is a chronic problem with many patients eventually returning to tobacco use (relapse). The variability in the definition of relapse creates difficulty in examining prolonged abstinence in studies. For some researchers, relapse may occur as quickly as one day after a patient begins a quit attempt, while other definitions include at least seven consecutive days of smoking. Smoking status can be assessed through self- or interviewer-administered questionnaires. Self-reported cessation rates can be validated by measuring expired carbon monoxide, saliva cotinine, or serum thiocyanate.

B. Discussion of evidence

1**. Questions:**

The development of an assessment in support of Medicare coverage decisions is based on the same general question for almost all requests: "Is the evidence sufficient to conclude that the application of the technology under study will improve net health outcomes for Medicare patients?"

CMS recognizes that the assessment of an intervention can depend substantially on how it is delivered, to whom it is applied, the alternatives with which it is being compared and the delivery setting. In this decision, CMS sought to address the following questions:

Is the evidence sufficient to conclude that smoking cessation counseling by health care practitioners will result in effective smoking cessation in the Medicare population?

Is the evidence sufficient to conclude that there is a relationship between counseling visit length, total time, and total number of sessions and effective smoking cessation counseling?

2. **External Technology Assessment**

CMS commissioned an evidence-based systematic review of smoking cessation as part of its Healthy Aging project in 1998. The final report was prepared by the Rand Corporation for CMS, entitled *Interventions to Promote Smoking Cessation in the Medicare Population*.[21] This document used the methods of the Southern California Evidence Based Practice Center, an Agency for Healthcare Research and Quality designated center for the review of evidence on the benefits and harms of health care interventions. While some of the questions posed were similar, or identical, to questions assessed by the PHS 2000 Guideline panel, the focus of the Rand report was on Medicare programs and policies. The ten questions specified by CMS for analysis and the resulting answers are as follows:

1. If Medicare were to offer a smoking cessation benefit, how would providers be reimbursed? For example, by minutes of counseling?
   There were no studies that compared smoking cessation outcomes as a function of different reimbursement programs.
2. How useful is provider training?
   Trained providers are significantly more likely to perform smoking-cessation tasks than untrained providers. Also, patients who saw trained providers were more likely to stop smoking than those who saw untrained providers (odds ratio of 1.48, 95% CI = 1.20 - 1.83)
3. What means can be used to curb overutilization? How effective are patient financial incentives?
   No studies were found that addressed curbing overutilization or the effect of capitation limits on services. The panel emphasized that overutilization should not be a problem, and that the area of concentration should be on convincing smokers to engage in cessation interventions. While full coverage of benefits resulted in more quitters, the most cost-effective benefit plans were those in which the patients bore some financial responsibility for the smoking cessation program.
4. How effective is counseling?
   All forms of counseling have statistically significant effects on smoking cessation, with individual counseling appearing to be more effective than group, telephone, and self help. There is a dose-response curve for length of time spent on each counseling session, number of sessions, and total duration of the counseling intervention.
5. How effective is pharmacotherapy?
   Nicotine replacement therapy was found to be more effective than control in smoking cessation, with an odds ratio of 1.72 (95% CI = 1.60 - 1.84). Buproprion was also found to be effective.
6. How effective is self-help?
   Self-help materials have a small practical effect on smoking cessation. There is no evidence that adding self-help materials to individual counseling or nicotine replacement therapy improved smoking cessation rates.
7. What practice settings are effective?
   In patients hospitalized with smoking-related illness, the highest quit rates were found among cardiac patients. In general, interventions with follow-up calls or visits were shown to be more successful than those without. A conclusion could not be drawn on the effectiveness of residential (inpatient) programs.
8. Who is most effective in delivering smoking cessation interventions?
   Many types of providers were found to be effective. In two of three comparative meta-analyses, physician providers had a higher estimated odds ratio of effectiveness compared to non-physician providers; one of the analyses was statistically significant.
9. Do certain interventions work better for special populations?
   The data was insufficient to answer this question.
10. Costs and cost effectiveness of interventions.
    Evidence suggests that smoking cessation interventions are highly cost-effective when compared with other medical treatments and prevention programs.

3. **Internal Technology Assessment**

These sources were reviewed for background information:

- Partnership for Prevention's NCD Request for Tobacco use Cessation Counseling
- Report of the U.S. Preventive Services Task Force *Guide to Clinical Preventive Services*, 2nd edition, 1996.
- The British Medical Journal's *Clinical Evidence*, June 2004, guidance on smoking cessation

Partnership for Prevention provided the following supporting information which was reviewed:

- PHS 2000 Guideline
  - Articles (44) supporting Tables 11,12, and 15 of the guideline
- Cochrane reviews (3)
  - Supporting articles (19)
- The Rand report prepared for CMS, 2000
  - Supporting articles (6)
- Older Smokers: randomized controlled trials and other references (44 articles)

Tobacco related websites at the CDC (including Surgeon General reports), NCI, and the Center for Tobacco Cessation were accessed. An independent literature review was accomplished. Pub Med was searched using combinations of the following terms: tobacco cessation, Medicare or elderly, with and without counseling (not previously mentioned information - 31 abstracts, 2 articles); tobacco cessation reimbursement, tobacco cessation cost effectiveness (7 articles); tobacco-drug interactions (10 abstracts, 1 article); Medicare claims and quality (2 articles); tobacco relapse (5 articles). Several counseling training websites were accessed with the search “tobacco cessation counseling training.” Some of the independently identified literature duplicated that provided by the Partners for Prevention. Additionally, the Department of Veterans Affairs, Department of Defense document, *Clinical Practice Guideline for the Management of Tobacco Use*, Update 2.0a June, 2004, was reviewed.

Discussion of evidence

Is the evidence sufficient to conclude that smoking cessation counseling by health care practitioners will result in effective smoking cessation in the Medicare population?

CMS reviewed evidence on four separate issues related to this question: 1) physician smoking cessation brief (3 minutes or less) counseling; 2) smoking cessation counseling in the elderly; 3) smoking cessation counseling by practitioners other than physicians; 4) relapse prevention, as it relates to both short and long term outcomes.

Physician smoking cessation brief counseling

The PHS 2000 guideline's meta-analysis used data from seven studies to examine brief advice.[22] Analysis results revealed an odds ratio of 1.3 (95% CI = 1.1 – 1.6) for physician advice to quit (attempt abstinence) as compared to no advice. The advice considered in this analysis was typically 3 minutes or less. The Cochrane review, with 16 randomized controlled trials, came to a similar conclusion about brief physician advice, with an odds ratio of 1.69 (95% CI = 1.45 - 1.98).[23] The British Medical Journal's *Clinical Evidence Concise* (Issue 11), states that advice from physicians and trained counselors to quit smoking is beneficial.[24] The U.S. Preventive Services Task Force Guide to Clinical Preventive Services, 2nd edition recommends cessation counseling on a regular basis.[25]

Smoking cessation counseling in the elderly

The PHS 2000 Guideline concludes that smoking cessation treatments have been shown to be effective for older adults, with strength of evidence category A (multiple well-designed randomized clinical trials, directly applicable to the recommendation, with consistent findings). In the PHS guideline's meta-analysis examining brief advice, five of the seven PHS Guideline studies either explicitly included seniors or could have included seniors based on participant description. In the PHS guideline's meta-analysis examining impact of counseling session length, 32 of 43 studies could have or explicitly did include those aged $\geq$ 65 years. The VA/DoD guideline update also recommends assessment and treatment of older tobacco users, with overall good quality of evidence.[26]

Several randomized controlled trials with older smokers have been published in peer-reviewed journals, some of which were included in the PHS 2000 Guideline analyses:

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- A randomized controlled trial by Vetter and Ford (1990) of 471 smokers age 60 years and over showed an improvement with counseling intervention as a single intervention by a general practitioner and a practice nurse.[27] Validated quit rates at 6 months were 14% in the intervention group versus 9% in the control ($p < 0.05$).
- A study by Rimer (1994) of 1,553 smokers age 50 to 70 years examined a self-help guide created for seniors (intervention group), versus a generic self-help guide (control group).[28] The intervention group was further subdivided into two groups, with one group having two brief (10 – 15 minute) phone calls in addition to the tailored guide. Patients were invited to call a quit line for additional help when needed. At the three month follow-up, those with the generic brochure had a quit rate of 7%, the tailored guide alone 9%, and for the tailored guide and calls 12%. A longer follow-up at 12 months showed that while the tailored guide improved the quit rates, the addition of the two calls did not significantly improve the outcome.
- A study by Morgan (1996) in 659 smokers aged 50 – 74 years compared usual care to physician delivered smoking cessation advice and counseling.[29] Enrolled subjects included all smokers, not only ones who were motivated to quit. Analyzed as intention to treat (follow-up and case ascertainment continued regardless of whether participants continued in the trial), smoking abstinence at 6 months was 15.4 percent in the intervention group versus 8.2 percent for usual care.
- Murray (2002) studied 11 year outcomes among 4,517 smokers randomized to an intensive counseling intervention versus usual care in a population who had existing evidence of airway obstruction (mean age 48.5, no upper limit exclusion).[30] In this study, the intensive intervention included an individual physician visit, a behavioral interview, a group orientation session, and group intervention sessions.[31] The odds ratio for long-term cessation was 4.45 (95% CI = 3.53 - 5.61). Ongoing intervention was provided, including a repeat program for participants who had relapsed.

These studies were also randomized controlled trials in older smokers, but had subjects with defined co-morbidities:

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- A study by Pederson (1991) randomized seventy-four hospitalized patients with COPD (mean age 53.4 years) to quit advice versus quit advice, self-help, and three to eight 15 to 20 minute counseling sessions.[32] Rates of cessation at 6 months were better in the intervention group (33.3% vs. 21.4%) but did not reach statistical significance.
- A study by Fagerberg (1998) looked at risk factor intervention in hypertensive men aged 50 to 72 with at least one of the additional risk factors: elevated cholesterol, diabetes, or smoking.[33] There were 148 patients (30% of the total study) enrolled as smokers, who were either randomized to the usual care group or intervention group. The intervention group's smoking cessation program started an initial physician visit, during which smoking habits, symptoms of diseases secondary to nicotine usage, psychological and social factors, and motivation for quitting smoking were discussed. After that, there were five weekly one hour meetings directed by a physician, using what is described as behavioral treatment principles. Nicotine gum was offered to the intervention group. The usual care group treatment was described as being according to normal clinical practice. Data were analyzed as intention-to-treat. After 3 years, the intervention group reported a 28% (n = 21) quit rate, while the usual care group reported an 11% (n = 8) quit rate. There was a differential total mortality rate between smokers and nonsmokers after 6.6 years. The smoker group had a mortality rate of 30.4% compared with 16.7% in nonsmokers (p = 0.0007).

There has been some suggestion in the literature that smoking cessation programs should be tailored based on certain group characteristics. For older adults, one of the barriers in treatment is that older smokers in general have smoked longer and tend to be more addicted than younger smokers.[11] Older smokers may believe that damage caused by smoking already had been done and there was no health benefit to cessation.[34] Additionally, in refractory smokers, there is some evidence that there is an increased occurrence of comorbid disorders that make these smokers less prone to successful treatment by a standard protocol.[35]

Evidence for cessation counseling by practitioners other than physicians

The PHS 2000 Guideline analyzed practitioner effectiveness using data from twenty-nine studies. Clinician type was compared to interventions where there was no clinician (e.g. no intervention or self-help materials). The estimated odds ratio for clinician counseling as compared to no clinician was 1.7 (95% CI 1.3, 2.1) for non-physician clinicians and 2.2 (95% CI 1.5, 3.2) for physician clinicians. In the meta-analytic review for advice to stop tobacco use and brief counseling mentioned above, there was insufficient evidence for other types of practitioners to be considered separately in these reviews. Individual studies have suggested that minimal advice offered by other types of clinicians is effective.

A Cochrane review looked at nursing interventions for smoking cessation.[36] Twenty randomized trials were selected to compare a nursing intervention with control or usual care. An estimated odds ratio of 1.47 (95% CI = 1.29 - 1.68) was calculated for the intervention as compared to control or usual care. The interventions were delivered by nurses or health visitors, with follow-up of at least six months. The reviews noted heterogeneity of study results, but use of a random effects model did not alter the statistical significance.

A meta-analysis by Mojica (2004) included 35 randomized controlled trials and 8 controlled clinical trials.[37] Only one of the studies directly compared the relative effectiveness of various practitioner types. The odds ratio for effectiveness by type of practitioner was estimated as follows:

- psychologist 1.94 (95% CI = 1.04 – 3.62)
- physician 1.87 (95% CI = 1.42 – 2.45)
- counselor 1.82 (95% CI = 0.84 – 3.96)
- nurse 1.76 (CI = 1.21 – 2.57)
- unknown 1.27 (CI = 0.57 – 2.82)
- other 1.18 (CI = 0.67 – 2.10)

Evidence for relapse prevention

The PHS 2000 Guideline states, “although a minority of tobacco users achieves permanent abstinence in an initial quit attempt, the majority persist in tobacco use for many years and typically cycle through multiple periods of relapse and remission.” The guideline states that most relapse occurs within the first three months after quitting, and recommends relapse prevention during this time. It further recommends that patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt (lowest strength of evidence rating, the panel came to a consensus on the recommendation without relevant randomized controlled trials).

Recommendations for relapse prevention by the VA/DoD guideline update:

- Relapse prevention should be addressed with every former tobacco user (expert consensus).
- Providers should address individual, environmental, and biopsychosocial factors associated with relapse (expert consensus).
- Patients with multiple relapses or who are having trouble in a current quit attempt in a clinical setting should be directed to more intense counseling programs or medication should be adjusted (fair evidence that the intervention may be useful/effective).

Is the evidence sufficient to conclude that there is a relationship between counseling visit length, total time, and total number of sessions and effective smoking cessation counseling?

CMS examined this evidence by separately considering counseling visit length, frequency, and total number as regards to effective smoking cessation counseling.

The PHS 2000 guideline concludes that there is a strong dose-response relation (relationship between the extent of counseling contact [dose] and the rate of abstinence [response]) between the intensity of tobacco cessation counseling and its effectiveness. Counseling treatment was defined as person-to-person contact, whether individual, group, or proactive telephone counseling. The dose-response statement of intensity of services in the PHS 2000 guideline is supported by three separate analyses: session length, session duration, and number of sessions.

Session length estimates in the PHS 2000 guideline are derived from a meta-analysis of 43 studies. Session length was categorized based on the maximum amount of time the clinician spent with the smoker discussing tobacco dependence in a single visit. Counseling intensity was divided into three groups: minimal counseling was defined as 3 minutes or less, low intensity counseling was defined as greater than 3 minutes up to 10 minutes, and higher intensity counseling was defined as greater than 10 minutes. The interventions could involve multiple visits, with the length of session determined as the longest session.

Table 1. Meta-analysis: Efficacy of and estimated abstinence rates for various intensity levels of person-to-person contact (n = 43 studies).

Level of Contact **Ratio (95% C.I.)**	**Number of Arms*** **(95% C.I.)**	**Estimated Odds**	**Estimated Abstinence Rate**
No contact	30	1.0	10.9
Minimal counseling (< 3 minutes)	19	1.3 (1.01–1.6)	13.4 (10.9–16.1)
Low intensity counseling (3 - 10 minutes)	16	1.6 (1.2–2.0)	16.0 (12.8–19.2)
Higher intensity counseling (> 10 minutes)	55	2.3 (2.0–2.7)	22.1 (19.4–24.7)

SOURCE: PHS 2000 Guideline
* treatment or control groups

A meta-analysis of thirty-five studies was used to assess the effect of total contact time in the PHS 2000 Guideline. The amount of contact time was the total time accumulated (session length times number of sessions). In some studies, the time was not known for those visits defined as minimal and low intensity interventions, so they were assigned lengths of 2 and 6.5 minutes. The accumulated visit time was then categorized into 6 categories (no contact, 1 – 3 minutes, 4 – 30 minutes, 31 – 90 minutes, 91 – 300 minutes, and greater than 300 minutes).

Table 2. Meta-analysis: Efficacy of and estimated abstinence rates for total amount of contact time (n = 35 studies).

Total Contact Time	Number of Arms*	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence Rate (95% C.I.)
No minutes	16	1.0	11.0
1 – 3 minutes	12	1.4 (1.1–1.8)	14.4 (11.3-17.5)
4 – 30 minutes	20	1.9 (1.5 -2.3)	18.8 (15.6-22.0)
31 – 90 minutes	16	3.0 (2.3-3.8)	26.5 (21.5-31.4)
91 – 300 minutes	16	3.2 (2.3-4.6)	28.4 (21.3-35.5)
> 300 minutes	15	2.8 (2.0-3.9)	25.5 (19.2-31.7)

SOURCE: PHS 2000 Guideline
* treatment or control groups

Data on number of sessions comes from forty-five studies in the PHS 2000 Guideline, with treatment number categorized as zero or one session, two to three sessions, four to eight sessions, and greater than eight sessions. A session was defined based on at least some person-to-person contact time, with exact session time varying.

Table 3. Meta-analysis: Efficacy of and estimated abstinence rates for number of person-to-person treatment sessions (n = 45 studies).

Number of Sessions	Number of Arms*	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence Rate (95% C.I.)
0 – 1 sessions	43	1.0	12.4
2 – 3 sessions	17	1.4 (1.1-1.7)	16.3 (13.7-19.0)
4 – 8 sessions	23	1.9 (1.6-2.2)	20.9 (18.1-23.6)
> 8 sessions	51	2.3 (2.1-3.0)	24.7 (21.0-28.4)

SOURCE: PHS 2000 Guideline
*treatment or control groups

The Cochrane review examining individual behavioral counseling for smoking cessation found “no evidence of benefit from more intensive compared to brief counselling, although the confidence intervals are wide and do not exclude the possibility of a clinically useful dose response effect (OR 0.98 95% CI 0.61 to 1.56)”.[38] The inclusion criteria for this review were different than the inclusion criteria for the PHS Guideline analyses. Furthermore, this review included a study where the intervention was additional to nicotine patch therapy, where the low-intensity arm had a 12-month quit rate of 25 percent, which may have decreased the difference between arms. When the high intensity is compared to the medium intensity interventions, a benefit is reported from increased contact (pooled OR 1.92, 95% CI 1.16 - 3.20). In another Cochrane review examining physician intervention, it was concluded that there was insufficient evidence to establish a significant difference in the effectiveness of advice based on the intensity of intervention, with more intensive interventions marginally more effective than minimal interventions.[23]

Evidence-based Guidelines

Two evidence-based guidelines were reviewed, the PHS 2000 Guideline and the Department of Veterans Affairs/Department of Defense *Clinical Practice Guideline for the Management of Tobacco Use* document, update version 2.0a, June, 2004.

PHS 2000 Guideline [http://www.surgeongeneral.gov/tobacco/]

The PHS 2000 Guideline is the product of a panel of government and private-sector experts representing the Agency for Health Care Research and Quality; National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute on Drug Abuse; Office on Smoking and Health at the Centers for Disease Control and Prevention; Robert Wood Johnson Foundation; and University of Wisconsin Medical School's Center for Tobacco Research and Intervention. Additionally, independent tobacco cessation experts provided peer review and consultation.

The key recommendations of the guideline are as follows:

1. Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.
2. Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:
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    - Patients willing to try to quit tobacco use should be provided with treatments identified as effective in the guideline.
    - Patients unwilling to try to quit tobacco use should be provided with a brief intervention designed to increase their motivation to quit.

3.

It is essential that clinicians and health care delivery systems (including administrators, insurers, and purchasers) institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting.

4.

Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.

5.

There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity (e.g., minutes of contact).

6.

Three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation:

- Provision of practical counseling (problem solving/skills training);
- Provision of social support as part of treatment (intra-treatment social support); and
- Help in securing social support outside of treatment (extra-treatment social support).

7.

Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be used with all patients attempting to quit smoking.

- Five first-line pharmacotherapies were identified that reliably increase long-term smoking abstinence rates:
  - Bupropion SR
  - Nicotine gum
  - Nicotine inhaler
  - Nicotine nasal spray
  - Nicotine patch
- Two second-line pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective:
  - Clonidine
  - Nortriptyline
-

  Over-the counter nicotine patches are effective relative to placebo, and their use should be encouraged.

8.

Tobacco dependence treatments are both clinically effective and cost-effective relative to other medical and disease prevention interventions. As such, insurers and purchasers should ensure that:

- All insurance plans include as a reimbursed benefit the counseling and pharmacotherapeutic treatments identified as effective in this guideline; and
- Clinicians are reimbursed for providing tobacco dependence treatment just as they are reimbursed for treating other chronic conditions.

Other findings in the guideline that are relevant to CMS's review and have not previously been mentioned include:

- Clinicians should be trained in effective tobacco cessation counseling (strong evidence - multiple well-designed randomized clinical trials, directly applicable to the recommendation, with consistent findings).
- The health risks of weight gain are small when compared to the risks of continued smoking.
- Three types of counseling and behavioral therapies result in higher abstinence rates (some evidence from randomized clinical trials supporting the recommendation, but the support was not optimal):
  - Providing smokers with problem solving skills/ skills training
  - Providing social support as part of treatment
  - Helping smokers obtain social support outside of treatment

The Department of Veterans Affairs/Department of Defense (VA/DoD) *Clinical Practice Guideline for the Management of Tobacco Use* document, update version 2.0a[26]

The VA/DoD guideline update 2.0a is a modification of the 1999 VHA/DoD Clinical Practice Guideline for the Management of Tobacco Use Cessation in the Primary Care Setting. The guideline recommendations were created by consensus from individuals at the VA, DoD, academia and guideline facilitators from the private sector. Published, peer-reviewed, randomized controlled trials were considered to be the strongest level of evidence in support of recommendations.

Key Elements of the VA/DoD guideline update:

1. Every tobacco user should be advised to quit.
2. Tobacco use is a chronic relapsing condition that requires repeated interventions.
3. Several effective treatments are available in assisting users to quit.
4. It is essential to provide access to effective evidence-based tobacco use counseling treatments and pharmacotherapy.
5. Collaborative tailored treatment strategies result in better outcomes.
6. Quitting tobacco leads to improved health and quality of life
7. Prevention strategies aim at reducing initiation, decreasing relapse, and eliminating exposure to environmental tobacco smoke.

The VA/DoD guideline update developed a specific counseling strategy with three levels of service, with minimal being 1 session of less than 3 minutes, intermediate being two to three sessions three to ten minutes, and intensive being four or more sessions of more than ten minutes.[26] The VA/DoD panel suggested this matrix to provide flexibility for the practitioner and patient. They stated that while intensive cessation programs are regarded as the most effective treatment available (finding good evidence that there is a dose response relationship between extent of counseling contact and rate of abstinence), these programs are currently used by only a small proportion of tobacco users.

Professional Society Position Statements

The PHS 2000 Guideline is endorsed and promoted by the American Medical Association, American Academy of Family Practitioners, Department of Defense, Veterans Administration, as well as several state tobacco prevention programs, including Arizona, Colorado, Maine, Massachusetts, Minnesota, New Mexico, Oregon, Washington, and Wisconsin. At least ten state Medicaid programs have used the guideline to design their own treatment benefit, treatment program, or clinician training.[39]

The protocol has been adopted as a covered benefit by the U.S. Department of Defense and U.S. Veterans Administration.[26] For federal employees, the Office of Personnel Management recommends that insurers cover tobacco use treatment consistent with the PHS guideline.[40] As an assessment of health plan performance criteria, cessation advice for current smokers is a measure employed by the National Committee on Quality Assurance. (www.ncqa.org/sohc2003/advising_smokers_to_quit.htm).

Public Comments

Public comments (80 total) overwhelmingly supported the request for Medicare coverage for tobacco cessation counseling. Over half of the comments expressed that Medicare should consider coverage of FDA-approved medications for tobacco cessation at the same time as coverage for cessation counseling is reviewed. Some suggested coverage of both prescription and over-the-counter medications. Non-coverage was sited as a barrier to treatment.

A letter was submitted by Partners for Effective Tobacco Policy, a coalition of more than 60 national organizations including the American Medical Association, the American Cancer Society, the American Heart Association, the American Lung Association and the Society for Research on Nicotine and Tobacco. Strong support for the NCD request was expressed. Comments included statements about the evidence that was presented to support the request, stating it was deemed as current and representing the best available science on this subject. Another comment included “it is important to note that tobacco cessation counseling services target those individuals who are suffering most and have a strong potential for improved health should they receive these services.”

The American Thoracic Society urged coverage not be limited to individuals who have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with tobacco-related disease. They also recommended that the cost be captured in the Sustainable Growth Rate formula. The National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control supported the current proposal and recommended considering coverage of other evidence-based treatments such as FDA-approved pharmacotherapy and proactive telephone counseling.

The American College of Chest Physicians recommended “specific guidelines and codes are needed for this complex, time-consuming, important behavior modification.” Additionally, they recommended that “the Medicare expenditures for these new services should be included as an allowance in the law and regulatory changes component of the Sustainable Growth Rate target.” Richard Hurt from the Mayo Clinic recommended coverage for residential treatment. Marc L. Steinberg, Ph.D., mentioned the issue of direct savings incurred from not purchasing tobacco if one quits, particularly for those on limited incomes.

CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

CMS focused on two general questions:

Is the evidence sufficient to conclude that smoking cessation counseling by health care practitioners will result in effective smoking cessation in the Medicare population?

Is the evidence sufficient to conclude that there is a relationship between counseling visit length, frequency, and total number and effective smoking cessation counseling?

Is the evidence sufficient to conclude that smoking cessation counseling by health care practitioners will result in effective smoking cessation in the Medicare population?

Results of meta-analyses in the PHS 2000 Guideline and the Cochrane review give statistically significant results for the effectiveness of brief physician cessation counseling. The CMS report came to the conclusion that all forms of cessation counseling are effective, as did the VA/DoD guideline. Cessation counseling is supported by the U.S. Preventive Services Task Force Guide to Clinical Preventive Services, British Medical Journal's *Clinical Evidence Concise*, and many professional societies. CMS concludes that there is sufficient evidence that brief physician cessation counseling is effective.

Randomized controlled trials have examined the effectiveness of smoking cessation counseling in the elderly. The PHS 2000 guideline concludes that smoking cessation treatments have been shown to be effective specifically in the elderly, and the VA/DoD guideline update recommends assessment and treatment of older tobacco users, based on adequate evidence. In examining studies done in the elderly, the interventions are extremely heterogeneous (as they are in tobacco cessation counseling studies for all ages). Additionally, many studies in the tobacco cessation literature lack the power to find a statistically significant difference between control and intervention, therefore meta-analysis can be useful. The evidence at this time does not support tailoring programs to specific groups. While CMS concludes that smoking cessation counseling does appear to be effective in the elderly, the most effective program for the elderly has not been clearly defined.

Several meta-analyses have looked at cessation counseling treatment comparing various clinicians. There is more data on some clinician types than others, causing difficulty in comparison and interpretation of results. In examining the current information, all types of clinician appear to be effective, with no one group appearing more effective

CMS concludes that the PHS 2000 Guideline provides a strong basis for allowing coverage of cessation counseling treatment. The PHS 2000 Guideline is based on the findings of many scientific trials. Panel members were comprised of government and private-sector experts who developed an evidence-based model and performed a comprehensive evaluation of the literature. A rigorous science-based methodology that included independent coding by reviewers, evidence tables, and meta-analyses was used to develop the recommendations. Reviews were done to evaluate the validity, reliability, and use of the guideline in the clinical environment. As a result, many national organizations support the use of the guideline. Furthermore, the PHS 2000 Guideline and the CMS report recommend training in cessation treatment. CMS concludes that training is necessary to provide effective cessation counseling.

Relapse is an important consideration in looking at both short and long term outcomes for patients. How long does the initial effect of successful quitting last? This seems a difficult question to answer. It is unclear what effective measures there are to prevent relapse. More research needs to be done in the optimal timing and types of relapse prevention interventions and the efficacy of various formats for relapse prevention treatments, as CMS is concerned with not only patients' initial cessation success but also long-term abstinence.

Overall, the evidence is sufficient to conclude that smoking cessation counseling by health care practitioners will result in effective smoking cessation in the Medicare population.

Is the evidence sufficient to conclude that there is a relationship between counseling visit length, frequency, and total number and effective smoking cessation counseling?

The PHS 2000 Guideline, the CMS report, and the VA/DoD guideline conclude that there is evidence to support a dose-response relationship between the length of time spent on each counseling session, number of sessions, and total duration of tobacco cessation counseling and its effectiveness. The evidence from the Cochrane reviews is in the same direction, but not as strong. As noted previously, there is much heterogeneity among studies and in general, lack of power to detect statistically significant differences in outcomes within individual studies. While we acknowledge that there is evidence for a dose-response relationship, there is no evidence to clearly delineate what is the most effective intensity or duration strategy in the Medicare population. Therefore, we propose a strategy based on the PHS guideline. Table 1 in this document provides evidence for three levels of contact: minimal counseling (< 3 minutes); intermediate counseling (3 – 10 minutes); and intensive counseling (> 10 minutes). Table 2 provides evidence for total time but with some caveats. We note in this table that the lower confidence interval limit for 31 - 90 minutes and 91 – 300 minutes are the same. Additionally, the estimated abstinence odds ratio for > 300 minutes actually decreases, to lower than the estimate for 31 – 90 minutes. Table 3 provides evidence for the number of sessions, with all 3 session groupings having a statistically significant estimated odds ratio.

Strategy	Counseling	Benefit
Minimal ≤ 3 minutes	1 session	Included in current E&M payment
Intermediate 3 to 10 minutes	2 – 3 sessions	Proposed new covered service
Intensive > 10 minutes	4 sessions	Proposed new covered service

The above strategy matrix is also very similar to that suggested by the VA/DoD Guideline Update. CMS concludes that while intensive cessation programs may be the most effective treatment available, we should also cover intermediate intensity cessation counseling to provide flexibility for the clinician and patient.

A significant consideration in the provision of cessation counseling services is the failure to maintain abstinence, and the best program to prevent relapse has not been identified. As suggested by the Partnership for Prevention, we propose covering up to two cessation attempts per year to help address the issue of relapse.

Costs and cost effectiveness

The Campaign for Tobacco-Free Kids estimated, assuming a two percent utilization rate of counseling and a 20 percent quit rate, that 187,000 Medicare beneficiaries would succeed in abstinence over a ten year period.[41] The average annual Medicare cost would be $11.2 million, with a ten-year Medicare cost of $112 million. The ten-year Medicare savings would be $75 million, with a ten-year non-Medicare savings of $62 million. Over this time, the combined savings to Medicare, state government healthcare programs, third party payers, and to health consumer's out-of-pocket costs, the total savings of the benefit would exceed the costs.

Conclusions

Tobacco cessation (abstinence) is an acceptable substitute endpoint for improved health outcomes, as it has been shown to improve health. Tobacco cessation counseling can be effectively delivered by adequately trained clinicians to the Medicare population. While a several types of clinician have been shown to be effective in cessation counseling, it is not clear that one type is more effective than another. Brief cessation advice for all smokers is desirable and can already be paid through the evaluation and management visits. Though brief advice is effective, the length of time spent on each counseling session, number of sessions, and total duration of tobacco cessation counseling are related to the degree of effectiveness. While acknowledging that a dose-response relationship is suggested, the most effective intensity and duration of treatment in the Medicare population of smokers is not clearly delineated. The basis of cessation counseling treatment should be the current PHS Guideline, due to the rigorous scientific methods used in its development and wide acceptance. Despite the effectiveness of cessation therapy, the failure of maintenance of abstinence is common. Relapse prevention is an important area where more knowledge is needed.

Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that smoking and tobacco use cessation counseling, based on the current PHS Guideline, is reasonable and necessary for a patient with a disease or an adverse health effect that has been found by the U.S. Surgeon General to be linked to tobacco use, or who is taking a therapeutic agent whose metabolism or dosing is affected by tobacco use as based on FDA-approved information. The counseling may only be providedby individuals trained in tobacco use cessation counseling.

Minimal counseling is already covered at each evaluation and management visit. Beyond that, Medicare proposes to cover 2 cessation attempts per year. Each attempt may include a maximum of four intermediate or intensive sessions, with the total annual benefit covering up to 8 sessions in a 12 month period. The practitioner and patient have flexibility to choose between intermediate or intensive cessation strategies for each attempt.

There is evidence that seniors have not been offered smoking cessation treatments at the same frequency as that of younger smokers. It is therefore desirable to evaluate the provision of tobacco dependence treatments in the Medicare population, similar to other performance-based measures.[42,43] CMS will provide well-defined and unique codes to allow the evaluation of per-capita rate of services provided. Additionally, specific codes will allow for the measurement of the processes, outcomes, and patient experiences.

CMS is requesting public comments on this proposed decision memorandum pursuant to Section 731 of the Medicare Modernization Act. After considering the public comments, we will issue a final decision memorandum.

Appendix

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

One of the goals of our determination process is to assess net health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

An intervention is not reasonable and necessary if its risks outweigh its benefits. Among other things, CMS evaluates whether reported benefits translate into improved net health outcomes. The direction, magnitude and consistency of the risks and benefits across studies are important considerations. Based on the analysis of the strength of the evidence, CMS assesses whether an intervention or technology's benefits to Medicare beneficiaries outweigh its harms.

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